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RESEARCH

Prospective multicenter real-world outcomes of Suction Technology Utility in Mini-PCNL Study (STUMPS) in modern-day practice: formulation of the global STUMPS registry on behalf of the endourology section of the European Association of Urology and the suction mini-PCNL collaborative study group

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Abstract

Purpose To present outcomes of a registry to understand the practice patterns, resource utilization, and nuances of suction mini-percutaneous nephron lithotripsy (SM-PCNL).

Methods Data from 30 centers in 21 countries were prospectively collected (March–November 2024). SM-PCNL was defined as PCNL using a suction nephrostomy sheath of size 14–22 Fr. with any lithotripsy device. There were no instructions on how to perform the surgical procedure. Stone features and stone-free status were assessed using an unenhanced CT scan. Data are presented as median/interquartile range and frequency/proportion.

Results 1707 patients were included and 42.4% of them were males. Most were first-time stone formers. Median age was 50 years. Median stone volume was 1700 mm^3. Surgery was commonly performed using a single access tract (92.9%) and in supine position (56.5%). The fluoroscopy-only puncture was used as the most common access (70.7%), followed by the combination of fluoroscopy and ultrasound (25.1%). Median operation time was 45 min. The most common sheath was Clearpetra (27.8%). Thulium fiber laser was the most frequent energy used (26.2%). A tubeless procedure with a stent was employed in 47.0% of cases. Most common complications were fever managed by observation (7.3%), fever requiring antibiotics (3.3%), blood transfusion (1.1%), and sepsis (0.2%). Median hospitalization was 3 days. 30-day CT scan showed zero fragments in 82.4% of patients. Reintervention was performed in 2.6% of cases.

Conclusions This registry outlines the various equipment, peri-operative strategies, complications, and outcomes of SM-PCNL performed in real-world practice, providing valuable data on the nuances of performing such surgery.

Keywords Kidney calculi · Lithotripsy · Percutaneous nephrolithotomy · Sheath · Suction

Introduction

Experimental and clinical evidence shows that vacuum and suction aspiration devices in percutaneous nephrolitothripsy (PCNL) are reforming the way this surgical intervention is being done [1, 2]. Adding suction to mini-PCNL reduces

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infectious complications and improves the stone-free rate (SFR) [1]. Suction or vacuum aspiration percutaneous access sheaths have been shown by Li et al. to significantly shorten the operative time and patient hospitalization, and reduce auxiliary procedures and complications [3].

Current nomenclature defines mini-PCNL as any PCNL using a sheath size not exceeding 22 Fr [4] with variable subset terminologies in the literature such as minimally invasive PCNL [5], Chinese minimally invasive mini-PCNL [6], ultra mini-PCNL [7], and super mini-PCNL [8]. Initially "mini perc" was described by Jackman et al. as an ideal less invasive alternative to PCNL and meant for small to medium-sized stones in normal kidneys [9]. With experience and expertise, super mini and mini-PCNL are now used in any renal stone volumes because of their low rate of complications, high SFR, and negligible need for blood transfusion vis a vis standard PCNL [10, 11]. It is the preferred procedure of choice, even for stones > 2 cm and standard PCNL is now mainly reserved for staghorn stones [10].

Whilst mini-PCNL is streamlined, the real-world practice has often differences. World over, urologists vary in mode of access, sheath size, tract dilatation technique, types of sheaths and nephoscopes, energy devices for lithotripsy, and even exit strategy. In modern times, the addition of suction, digitalization, the introduction of single and reusable devices, and patient positioning have further changed the outcomes of surgery.

In this study, we collated a registry to report the practice patterns and utility of suction sheath technology in real-world practice. We also reported how surgeons utilize different suction devices and energy sources and their influence on perioperative outcomes of mini-PCNL.

Material and methods

In this study, the definition of suction mini-PCNL procedure is PCNL done using single-use or reusable percutaneous suction access nephrostomy sheath (14–22 Fr) with any energy device for lithotripsy as was also endorsed by the International Alliance of Urolithiasis [4]. Anonymized data were collected for the Suction Technology Utility in mini-PCNL Study (STUMPS) registry which was managed by the Asian Institute of Nephro-Urology after ethical board clearance under protocol (AINU #01/2024). Adult patients with kidney stone(s) only were prospectively enrolled between March and November 2024 from 30 centres, in 21 countries (Supplementary Fig. 1). Inclusion and exclusion criteria are summarised in Supplementary Table 1. Patients with missing data were also excluded. Patient baseline characteristics, stone features, operative techniques, lithotripsy modality, surgical time, complication, SFR, and reoperation rate were gathered. Stone features were assessed using a 2 mm slice unenhanced low-dose CT scan with bone window performed within 6–8 weeks before surgery. This setting is better than the soft-tissue window and large slice thickness and leads to more accurate results [12]. Stone diameter was gathered on the largest diameter of single or multiple stones. Stone Volume (of the largest stone in case of multiplicity) was estimated using an ellipsoid formula (length*width*depth*π*0.167). Guy's stone score was also calculated. All patients had a preoperative urine culture and infections were treated with an appropriate course of antibiotics according to sensitivity. Antibiotic prophylaxis was given according to local practice. Anticoagulants/antiplatelets were stopped 3 to 7 days before surgery and restarted according to each clinical case. There were no instructions on how to perform the surgical procedure and surgeons were allowed to perform suction mini-PCNL as per their practice but respecting inclusion and exclusion criteria. Surgeons were asked to grade their experience of suction use at the end of each case using a 5-point Likert-type scale (1 = excellent; 2 = very good; 3 = good; 4 = average; 5 = difficult). Complications within 30 days of surgery were graded according to Clavien score for Percutaneous Nephrolithotomy [13]. Pain score was assessed on the first postoperative day using a 10-point visual analog scale where 1 was the lowest score.

Postoperatively, all patients had a low dose non-contrast CT scan for uniform assessment of residual fragment (RF) using bone window. Stone-free status was graded as:

Grade A: no fragment.

Grade B: single fragment ≤ 4 mm.

Grade C: single fragment > 4 mm or multiple fragments of any size.

Statistical analysis

Data are presented as median and interquartile range for continuous variables and as frequency and proportion for categorical variables. All statistical tests were performed using R version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

During the study period, 1707 patients who met the inclusion criteria were included. Table 1 shows patients' baseline characteristics. There were 723 (42.4%) men. The median age was 50 (39–61) years. Most of the patients had ASA scores of 1 (53.8%) and 2 (37.0%). Median BMI was 26 [23–29]. Pain was the most frequent symptom indication for intervention (73.2% of patients). Indication for PCNL was an incidental finding of stones in 14.5% of the cases. Most patients were first-time stone formers (75.2%). Intervention

Table 1 Patients' baseline characteristics

	n = 1707
Age, years, median [IQR]	50 [39, 61]
Male gender, n (%)	723 (42.4)
ASA score, n (%)	
1	918 (53.8)
2	632 (37.0)
3	150 (8.8)
4	7 (0.4)
Body mass index, kg/m^2, median [IQR]	26 [23, 29]
Diabetes Mellitus, n (%)	317 (18.6)
Chronic kidney disease, n (%)	361 (21.1)
Anticoagulant/antiplatelet use, n (%)	202 (11.8)
(stopped 3–7 days before surgery)	
Presentation, n (%)	
Hematuria	130 (7.6)
Pain	1250 (73.2)
Fever	79 (4.6)
Incidental	248 (14.6)
First time stone former, n (%)	1283 (75.2)
Positive pre-operative urine culture n (%)	350 (20.5)
Laterality	
Left	833 (48.8)
Right	782 (45.8)
Bilateral	92 (5.4)
Guy's stone score n (%)	
1	888 (52.2)
2	496 (29.2)
3	218 (12.8)
4	98 (5.8)
Hounsfield units, median [IQR]	1170 [923, 1354]
Largest stone diameter, cm, median [IQR]	2.0 [1.5, 2.7]
Stone volume, mm^3, median [IQR]	1700 [911, 3540]
Kidney anatomy, n (%)	
Normal	1417 (83.0)
Malrotated	188 (11.0)
Horse shoe kidney	25 (1.5)
Ectopic	5 (0.3)
Duplex	72 (4.2)
Previous Percutaneous nephrolithotripsy, n (%)	67 (3.9)
Final stone composition on analysis n (%)	
Not performed	371 (21.7)
Calcium phosphate	391 (22.9)
Calcium oxalate monohydrate	330 (19.3)
Calcium oxalate dihydrate	186 (11.0)
Infectious	85 (5.0)
Uric acid	24 (1.4)
Others	320 (18.7)

IQR interquartile range, *ASA* American Society of Anesthesiologists

for bilateral stones was performed in 92 (5.4%) of patients. Guy's stone scores of 1 (52.2%) and 2 (29.2%) were the most common stone burden but the procedure was also used in Guy's 3 and 4 score stone. Median stone volume was 1700 [911–3540] mm^3 and median stone density was 1170 [923–1354] Hounsfield units. Only 67 (3.9%) patients had a history of previous PCNL. There were 290 (17%) patients with anomalous kidneys.

Table 2 shows intraoperative characteristics. Surgery was done in spinal anesthesia in 783 (45.9%) patients, with the supine position as the most common in 56.5% of the cases, followed by prone in 41.1% and semi-lateral in the rest ones. Supracostal access above the 11 th rib was necessary for 449 (26.3%) patients. The fluoroscopy-only puncture was used as the most common access in 70.7% of the cases, followed by the combination of fluoroscopy and ultrasound (25.1%). Only one tract was sufficient in most cases (92.9%) and tract dilatation was performed in a single step in half of the cases (55.5%), followed by a serial dilatation with metal (31.4%). The most common single-use vacuum sheath was Clearpetra (Wellead, Guangzhou, China) used in 475 (27.8%) cases. Thulium fiber laser was the most frequent laser energy used (26.2%) followed by low-power Holmium laser (23.0%) and Swiss lithoclast master (EMS, Nyon, Switzerland) (Supplementary Fig. 2). Regarding the lithotripsy modality, the fragmentation-only technique was the most performed (58.8%). Basket utilization to extract fragments was noted in only 437 (25.6%) procedures. One tract was enough to access and clear all stones in 92.9% of cases. However, we could not document if an additional maneuver like flexible nephroscopy was also used. Regarding sheath maneuverability, surgeons were able to reach all parts of the pelvic caliceal system in 84.3% of cases from a single access. Indeed, in a selected few cases a second puncture was needed. Suction/vacuum worked well in 99.0% of the procedures and in the rest of the cases, the malfunction was due to an issue with wall suction. Median Likert scale evaluation for sheath performance was scored 1 [1, 2] for both ease of suction and visibility, and 2 [1, 2] for manipulation, meaning excellent for ease of suction and visibility, and very good for manipulation.

Regarding the exit strategy, a tubeless procedure with a stent was performed in 802 (47.0%) patients, a nephrostomy tube with a stent was placed in 484 (28.4%) patients, and a totally tubeless procedure was done in only 19 (1.1%) patients. Grade A intraoperative stone-free status by fluoroscopy and visual inspection was seen in 1392 (81.7%). The median lithotripsy time was 18 [9–30] minutes and the median operation time was 45 [30–75] minutes.

Table 2 Procedural characteristics

	n = 1707
Spinal anesthesia, n (%)	
Patient position, n (%)	783 (45.9)
Prone	701 (41.1)
Supine	965 (56.5)
Semilateral	41 (2.4)
Puncture modality, n (%)	
Fluoroscopy only	1207 (70.8)
USG only	43 (2.5)
Fluoroscopy + USG	429 (25.1)
Endoscopy guided	26 (1.5)
Laparoscopic guided	2 (0.1)
Number of tracts, n (%)	
1	1585 (92.9)
2	115 (6.7)
3	6 (0.3)
4	1 (0.1)
Supracostal access (above 11 th rib), n (%)	449 (26.3)
Tract dilation method, n (%)	
Serial with metal dilators	536 (31.4)
Serial with non-metal dilators	183 (10.7)
Balloon	40 (2.3)
Single step dilatation	948 (55.6)
Safety wire inserted during surgery, n (%)	710 (41.6)
Sheath size, n (%)	
20–22 Fr	189 (11.1)
14–18 Fr	1518 (88.9)
Sheath brand, n (%)	
Clearpetra	475 (27.8)
Shah	600 (35.1)
Others[a]	632 (37.1)
Energy employed for lithotripsy, n (%)	
Holmium Low Power (≤ 30w)	392 (23.0)
Holmium High Power (> 30w)	305 (17.9)
Thulium Fibre laser	447 (26.2)
Pulsed Thulium:YAG laser	33 (1.9)
Trilogy	25 (1.5)
EMS with suction	4 (0.2)
Lithoclast master	196 (11.5)
Pneumatic	277 (16.2)
More than one energy type	18 (1.1)
Lithotripsy modality, n (%)	
Fragmentation only	933 (58.8)
Dusting only	67 (4.2)
Popcorning only	2 (0.1)
Combination of the above	585 (36.9)
Basket required for stone extraction, n (%)	437 (25.6)
Lithotripsy time, minutes, median [IQR]	18 [9, 30]
Total operation time, minutes, median [IQR]	45 [30, 75]
Sheath change required, n (%)	0
Single access able to visualise all parts of kidney including lower pole, n (%)	1313 (84.3)
Intraoperative SFR by surgeon confirmed by fluoroscopy or visual inspection, n (%)	
100% clear	1392 (81.7)
Only dust remains	239 (14.0)
Fragments remain	73 (4.3)
Exit strategy, n (%)	
Tubeless with nephrostomy tube	260 (15.2)
Tubeless with stent	802 (47.0)
Tubeless with overnight ureteric catheter	142 (8.3)
Nephrostomy tube and stent	484 (28.4)
Totally tubeless	19 (1.1)
Tract closure modality, (%)	
No stitch	715 (41.9)
Stitch placed	972 (56.9)
Hemostatic agent	20 (1.2)
Likert scale evaluation, median [IQR]	
Ease of suction	1 [1, 2]
Manipulation	2 [1, 2]
Visibility	1 [1, 2]

Fr French, *IQR* interquartile range

[a]Customized Metal suction; Urologeman sheath; 18 Fr multifunction suction sheath by Hawk

Table 3 shows intraoperative and postoperative outcomes. Only 5 (0.3%) patients had intraoperative bleeding for which the procedure was abandoned midway. Twenty-two (1.3%) patients had an intraoperative injury of the collecting system managed by simple nephrostomy tube placement. Median day one postoperative VAS score was 2.0 [1.0–3.0]. Median post-operative hospital stay was 3 [2–4] days.

Regarding postoperative complications, fever (> 38° C) managed by observation without antibiotics (Clavien 1) was noted in 125 (7.3%) patients, while fever requiring antibiotics (Clavien grade 2) in 56 (3.3%) patients. Blood transfusion (Clavien 2) was necessary for 18 (1.1%) patients. A colonic injury managed conservatively (Clavien 3a) and a pleural injury needing a chest tube (Clavien 3a) occurred in 2 (0.1%) and 10 (0.6%) of the cases, respectively. Sepsis needing intensive care management (Clavien 4b) occurred in only 4 (0.2%) patients. Readmission for any reason within 72 h of discharge was noted in 28 (1.6%) patients. No mortality was reported. 30-day CT scan showed Grade A stone-free status in 1406 (82.4%) patients. Reintervention was planned in 44 (2.6%) patients of whom 63.6% had flexible ureteroscopy.

Table 3 Intraoperative and postoperative outcomes

	Overall (N = 1707)
Intraoperative bleeding after dilatation, n (%)	
No bleeding	1452 (85.1)
Oozing partially obscuring vision despite suction but allowing surgery to continue	79 (4.6)
Heavy bleeding needing to discontinue surgery (case abandoned)	5 (0.3)
Postoperative complications, n (%)	
Postoperative fever (> 38° C) managed by observation without antibiotics (Clavien grade 1)	125 (7.3)
Blood transfusion (Clavien grade 2)	18 (1.1)
Bleeding requiring multiple bladder washouts/irrigations (Clavien grade 2)	9 (0.5)
Postoperative fever (> 38 °C) managed with antibiotics in the ward	56 (3.3)
Collecting system perforation needing nephrostomy tube placement (Clavien grade 3a)	22 (1.3)
Colonic injury on managed conservatively (Clavien grade 3a)	2 (0.1)
Pleural injury on needing chest tube (Clavien grade 3a)	10 (0.6)
Bleeding managed by angioembolisation (Clavien grade 3b)	1 (0.1)
Sepsis with multiple organ failure needing intensive care management (Clavien grade 4b)	4 (0.2)
Readmission for any reason within 72 h from discharge, n (%)	28 (1.6)
Postoperative pain score, median [IQR]	2.0 [1.0, 3.0]
Hospital stay, days, median [IQR]	3 [2, 4]
Postoperative RF grade on 30 day CT scan, n (%)	
Grade A (no fragment)	1406 (82.4)
Grade B (single fragment ≤ 4 mm)	216 (12.7)
Grade C (single fragment > 4 mm or multiple fragments of any size)	85 (5.0)
Reintervention for residual fragment(s) after 30 days, n (%)	44 (2.6)
Time to reintervention after 30 days of the index procedure, days, median [IQR]	4 [1, 6]
Reintervention modality, n (%)	n = 44 (2.2%)
Shock wave lithotripsy	2 (4.6)
Retrograde intrarenal surgery	28 (63.6)
Percutaneous nephrolithotripsy	6 (13.6)
Endoscopic combine intrarenal surgery	8 (18.2)

IQR interquartile range

Discussion

PCNL, first described in 1976 [14], has since evolved as a time-tested, guideline-established modality for renal stones, in all ages and renal anatomies. Compared to standard PCNL, the use of mini-PCNL is associated with better operative and patient-reported outcomes. This evidence was obtained due to sustained collective effort by the evaluation of a prospective database by CROES that captured non-suction PCNL data on 5803 patients between 2007 and 2009 and provided high-level evidence [15]. In fact, the utility of registries in urology has proven how surgery, despite being standardized, is adopted and adapted in the real world across different geographies. As technical innovations develop this has a direct bearing on the surgical outcomes of real-world practice [16, 17]. Mini-PCNL is one such surgery since inception that continues to transform as technological innovations, like suction and aspiration, push its boundaries, even making it the preferred choice in stones > 2 cm, alongside flexible ureteroscopy and shock wave lithotripsy [18]. With the availability of a variety of sheaths, the option of supine and prone position, the integration of different energy sources for lithotripsy, and a better understanding of suction dynamics, the EAU Endourology research group took the initiative to formulate a prospective registry, based on real-world practice to assimilate data specific to suction or vacuum assisted mini-PCNL. To our knowledge, this is the first of its kind in a real-world global registry.

It is evident that suction mini-PCNL is still practiced as a standard of care worldwide in all renal stones and anatomies, despite other suction modalities, such as the flexible and navigable suction ureteral access sheath, are gaining momentum for kidney stone disease management. In fact, in a worldwide survey of 632 urologists, 55.4% of responders have already adopted suction PCNL in their practice as it helps to improve SFR and importantly minimize infective complications [10]. In our study too, 1406 (82.4%) patients had a 30-day CT proven zero residual fragments, a remarkable achievement considering there were complex renal stones, anomalous kidneys, and even customized metal reusable and disposable sheaths used in a multicentre practice with a myriad of lithotripsy equipment. Yet, our results show that the postoperative complication rate was low and most of the complications were of low grade (i.e. Clavien ≤ 2). This is a testament that the outcomes of suction mini-PCNL surgery are, if not the gold standard, unmatched by other suction-based technology. Zero fragment was achieved in flexible ureteroscopy using suction sheaths as well but that was performed only by experts and in normal renal anatomy [19]. In modern endourology, unenhanced CT scan is considered the gold standard for SFR estimation both in PCNL and FURS [20, 21] and, despite variable practices, all surgeons were able to standardize reporting. This is also the first time for a multicenter PCNL registry. We believe that not only they should achieve zero fragments but modern endourology armamentarium should additionally ensure negligible complications as the benchmarks when managing any renal stone in any kidney anatomy. We also reported zero mortality and just 2.2% reintervention. This heralds the STUMPS registry as a possible new reference study for any suction technology to match, as it has all types of adult kidneys and stone burdens with proven CT scans, using any current manufactured equipment for suction mini-PCNL, including customized metal suction 18 Fr sheath, something not been reported before. We do acknowledge the absence of shock pulse device, as that was not reportedly used in our series. Perhaps this is only an incidental omission as centers did not use the same because it has been proven that both trilogy and shock pulse are equally effective in PCNL [22]. It could also be an outcome reflective of an increased adoption of different laser types in mini-PCNL. In our registry, all forms of laser energy devices made by different companies were used independently. It is perhaps time to re-examine if lasers are an equally effective energy source unlike previous impressions, where the Holmium laser was a less effective tool in PCNL vis a vis no laser devices [23].

This study has some limitations. As it is beyond the scope of one single article, the STUMPS registry now provides data that needs analysis to gain information on the most favorable perioperative strategies that can probably make suction mini-PCNL the most efficient tool for percutaneous management of kidney stone disease and this must be validated with further randomized controlled and comparative studies to provide a basis for adoption into clinical practice. The absence of a comparative arm makes this study unidirectional. We also understand that certain surgeons may have more experience and hence the biases in outcomes favoring a certain stone subset. Yet, this is a prospective database of only one single modality in a real-world practice that throws many useful insights into the current state of practice of suction mini-PCNL world over. Considering that 21 countries participated in this study, STUMPS shows how widespread the adoption of this technology has gone from its introduction in less than a decade. Another limitation is the inability to get insights into suction and irrigation pressure settings and the influence they had intraoperatively. Indeed, this is crucial for a seamless surgery. Finally, the sample from each country included in this registry could not represent the majority of the country. Nevertheless, the STUMPS registry truly echoes the yesteryear clarion statement that "Serendipity, innovations in renal access, optics, radiology, and improvements in lithotripsy all contributed to the modern day PCNL" now should read as modern-day suction mini-PCNL [24].

Conclusion

To our knowledge, STUMPS is the first prospective global suction mini-PCNL registry outlining the various equipment, peri operative strategies, and detailing the complications, yet reporting outcomes in a standardized imaging format in real-world practice. The registry provides valuable data and when analyzed further will give us a more in-depth understanding of the nuances in performing suction mini-PCNL.

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Data availability Data is available on request from the corresponding author.

Declarations

Conflict of interest The authors declare no competing interests.

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